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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,859	12/09/2003	Anand R. Baichwal	540.1020c3	6846

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,859	BAICHWAL, ANAND R.	
	Examiner	Art Unit	
	James W. Rogers	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/09/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/04/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 12/09/2003 has been considered.

Claim Objections

Claim 27 is objected to because of the following informalities: "f" and "th" are typos the examiner believes the applicant meant "of" and "the" and used these words in place of the typos. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear to the examiner what weight ratio is being used in claim 19, is the ratio NSAID/(xanthan gum + locust bean gum) or is the ratio (xanthan gum + locust bean gum)/NSAID the examiner chose the latter for examination purposes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal (US 5,330,761).

Baichwal discloses a controlled release tablet and the method to produce it (including wet granulation) that includes an insoluble NSAID (e.g. Methyl salicylate), xanthan gum with the crosslinking agent locust bean gum and an inert diluent. See col 2 lin 33-37, col 3 lin 13-16, col 6 lin 31-32 and col 7 lin 39-62. Regarding claims 1,10,18-19,21,24 and 27 the amount of NSAID or ibuprofin used was met because Baichwal says "the particular amount of acitive agent included will, of course depend upon the particular agent and its intended use", so it is obvoious that one of ordinary skill in the pharmaceutical art will vary the amount of active ingredients depending on its intended use. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). Regarding claims 1,10 and 18 the dissolution as measured by a USP Type II (Paddle) Method limitation is met because the claimed tablet compositions encompass the same scope it would be obvious that their dissolution properties would be the same since the same composition would have the same properties. Regarding the use of ibuprofin as the insoluble NSAID, it is the position of the examiner that one of ordinary skill in the pharmaceutical art

would know that ibuprofen is a well known anti-inflammatory agent and would therfore be motivated to use it in the dosage form disclosed by Baichwal. Regarding claims 19-20,22-25,26 and 28 which deal with the amount of ingredients in the tablet and the amount of ingredients compared to each other, the Baichwal patent teaches a very broad range of percentages of the ingredients in the excipient which fall within the limitations claimed by the applicant and the patent also discuses that the ratio of the heteropolysacchardide gum (xanthan gum) to the homopolysaccharide gum (locust bean gum) are about 1:3 to 3:1, within the range specified by the applicants. See col 3 lin 1-3 and lin 54-59.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal (US 5,330,761) in view of Kuhrts (US patent 5,096,714).

The Baichwal patent is described as above.

The Baichwal patent does not specifically mention ibuprofen as an active ingredient and is silent on the exact amount of active ingredient in mg.

The Kuhrts patent describes a sustained release dosage tablet comprising up to 700 mg of ibuprofen (reads on about 800 mg in claim 21) and an effective amount of sustained release carrier, in an amount effective to provide prolonged and effective release of the drug. See claim 1 and ex 10.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Baicwal teaches all of the claimed invention in applicants claims except specifically mentioning the active ingredient ibuprofen and its concentration while the

Kuhrts patent discloses the use of ibuprofen within the range claimed by applicants in a slow release tablet. The motivation to combine the two documents would be the formulation of a pharmaceutical tablet formulation with the following ingredients ibuprofen, xanthan gum with the cross-linking agent locust bean gum and an inert diluent, all within a specified concentration. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 22-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,093,420. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-28 are generic to all that is recited in claims 1-46 of U.S. Patent No. 6,093,420. That is, claims 1-46 of U.S. Patent No. 6,093,420 falls entirely within the scope of claims 1-26 or in other words, claims 1-26 are anticipated by claims 1-46 of U.S. Patent No. 6,093,420. Specifically both claim a tablet comprising ibuprofen, xanthan gum, locust bean gum and an inert diluent, in which both dissolve at the same rate when measured by a USP Type II (Paddle) Method. Also both claim mostly the same concentrations, ratios and percentages or at least they are within the ranges specified for the above ingredients.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER